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K033079

Summary of Safety and Effectiveness Information
Chlamydia IgG ELISA Test Kit

I. Trinity Biotech
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Date of preparation: Nov. 20, 2003

II. Description of Device

The Chlamydia IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for qualitative detection of IgG antibodies inhuman serum to *Chlamydia* for the determination of immunological experience.

The Chlamydia IgG ELISA test is an enzyme linked immunosorbent assay to detect IgG antibodies to Chlamydia. Purified Chlamydia antigen (strain LGV II) is attached to a solid phase microtiter well. Diluted test sera are added to each well. If the antibodies are present that recognize the antigen, they will bind to the antigen in the well. After incubation, the wells are washed to remove unbound antibody. An enzyme labeled anti-human IgG is added to each well. If antibody is preset it will bind to the antibody attached to the antigen on the well. After incubation, the wells are washed to remove unbound conjugate. A substrate solution is added to each well. If enzyme is present, the substrate will undergo a color change. After an incubation period, the reaction is stopped and the color intensity is measured photometrically, producing an indirect measurement of specific antibody in the patient specimen.

III. Predicate Device

The Chlamydia IgG ELISA test is substantially equivalent to IFA. Equivalence is demonstrated by the following comparative results:

Performance Characteristics

1. % Agreement Positive and % Agreement Negative. Two different sites compared the Trinity Biotech Chlamydia IgG ELISA test relative to a commercial IFA kit. The two sites were R&D laboratories at commercial companies located in Maryland and New York, and affiliated with the manufacturer of the kit. The sera were from normal individuals of various ages, gender, and geographical areas. The results of the studies are compiled and summarized in Table 1. None of the performance characteristics were established with specimens from patients having documented chlamydia infections.

Table 1
Comparison of Chlamydia IgG ELISA and IFA

Trinity Biotech Chlamydia IgG ELISA

		+	eq	-	Total
Chlamydia IFA	**+ > 1:8**	81	7	7	95
	- < 1:8	5	9	246	260
	Total	86	16	253	355

% Agreement positive = 81/88 = 92.1% 95% Confidence Interval = 86.3% - 97.8%
% Agreement negative = 246/251= 98.0% 95% Confidence Interval = 96.2% - 99.8%
% Agreement = 327/239= 96.5% 95% Confidence Interval = 94.5% - 98.5%

Equivocals were not included in the above calculations.
The 95% Confidence Intervals were calculated using the normal method.

Please be advised that "% agreement positive" and "% agreement negative" refer to the comparison of this assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison assay's accuracy to predict disease.

2. Precision. Seven sera were assayed ten times each on three different assays at two different sites. Both sites were affiliated with the manufacturer of the kit. The inter and intra assay precision for each site is presented in Tables 2 and 3 and the inter-site precision is shown in Table 4. With appropriate technique the user should obtain precision of < 15% CV.

Table 2
Trinity Biotech Chlamydia IgG ELISA Intra- and Inter-Assay Precision
Study 1

	Assay 1 (n = 10)			**Assay 2 (n = 10)**			**Assay 3 (n = 10)**			**Inter-Assay(n=30)**		
Sera #	**X**	**SD**	**CV**	**X**	**SD**	**CV**	**X**	**SD**	**CV**	**X**	**SD**	**CV**
1	2.86	0.152	5.32%	2.97	0.076	2.57%	3.13	0.115	3.69%	2.99	0.162	5.42%
2	1.71	0.101	5.91%	1.88	0.098	5.20%	1.90	0.092	4.89%	1.83	0.129	7.05%
3	1.74	0.107	6.15%	1.87	0.071	3.78%	1.95	0.072	3.67%	1.85	0.121	6.50%
4	1.78	0.126	7.07%	1.92	0.053	2.77%	2.03	0.075	3.72%	1.91	0.135	7.06%
5	1.06	0.051	4.83%	1.12	0.034	3.00%	1.16	0.049	4.24%	1.11	0.060	5.42%
6	0.34	0.032	9.59%	0.32	0.042	13.06%	0.37	0.052	14.25%	0.34	0.046	13.55%
7	0.30	0.061	19.95%	0.29	0.056	19.43%	0.33	0.043	12.81%	0.31	0.054	17.75%

Table 3
Trinity Biotech Chlamydia IgG ELISA Intra- and Inter-Assay Precision
Study 2

Sera	Assay 1 (n = 10)			Assay 2 (n = 10)			Assay 3 (n = 10)			Inter-Assay(n = 30)		
#	X	SD	CV	X	SD	CV	X	SD	CV	X	SD	CV
1	3.08	0.052	1.69%	3.11	0.106	3.40%	3.00	0.117	3.91%	3.06	0.104	3.41%
2	1.77	0.085	4.80%	1.78	0.073	4.10%	1.75	0.094	5.38%	1.77	0.084	4.75%
3	1.86	0.062	3.35%	1.85	0.086	4.63%	1.86	0.083	4.46%	1.86	0.076	4.08%
4	1.81	0.060	3.30%	1.84	0.112	6.12%	1.84	0.102	5.52%	1.83	0.091	4.98%
5	0.93	0.051	5.46%	0.93	0.071	7.69%	0.94	0.053	5.61%	0.93	0.058	6.19%
6	0.04	0.014	31.17%	0.03	0.018	53.59%	0.06	0.024	39.50%	0.05	0.022	46.90%
7	0.05	0.016	35.60%	0.05	0.015	32.60%	0.07	0.032	47.62%	0.05	0.024	45.41%

Table 4
Trinity Biotech Chlamydia IgG ELISA Inter-Site Precision Study

	Inter-Site (n = 60)		
Sera #	X	SD	CV
1	3.03	0.140	4.63%
2	1.80	0.112	6.24%
3	1.86	0.100	5.37%
4	1.87	0.121	6.46%
5	1.02	0.110	10.73%
6	0.19	0.153	78.91%
7	0.18	0.137	75.20%

X = Mean
SD = standard deviation
CV = coefficient of variation = SD/X x 100
The methods in NCCLS EP5 were utilized for precision parameters.

3. Paired Serum Analysis

Nine serum pairs showing a greater than 4-fold increase in Complement Fixation (CF) titer or seroconversions by CF were assayed on the Trinity Biotech Chlamydia IgG ELISA assay. Each serum pair was evaluated to determine a seroconversion in antibody (acute negative and convalescent positive). Four pairs demonstrated a seroconversion by ELISA. Therefore the assay showed a % agreement positive of 44% (4/9) in demonstrating a seroconversion when the CF showed a 4-fold increase or a seroconversion.

4. Reproducibility Study

Fifty different sera with various levels of activity were assayed at three different sites. Two sites were R&D laboratories at commercial companies located in Maryland and New York. The third site was a large clinical laboratory located in Pennsylvania. The data from the three sites show good correlation with ISR values with Pearson product moment correlation coefficients of >0.989 between the sites. Excluding equivocals (n = 13), four determinations varied from their expected result (negative results for a positive specimen) giving a percent agreement of expected results between the three sites of 97.1% (133/137). The expected results were derived from previous Trinity Biotech ELISA testing of the samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 26 2003

Ms. Bonnie B. DeJoy
Director, Quality Systems
Trinity Biotech USA
P.O. Box 1059
Jamestown, NY 14702-1059

Re: k033079
Trade/Device Name: Captia Chlamydia IgG ELISA
Regulation Number: 21 CFR 866.3120
Regulation Name: Chlamydia serological reagents
Regulatory Class: Class I
Product Code: LJC
Dated: September 17, 2003
Received: September 29, 2003

Dear Ms. DeJoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K033079

Device Name: Trinity Biotech Captia™ Chlamydia IgG ELISA

Indications For Use: The Trinity Biotech Captia™ Chlamydia IgG ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for qualitative detection of IgG antibodies in human serum to *Chlamydia* for the determination of immunological experience.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 XFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033079